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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,321	11/22/2000	Richard A. Shimkets	15966-599 (CURA-99)	3118

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	16

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/718,321	Applicant(s) SHIMKETS ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to an isolated polynucleotide or oligonucleotide, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is required.

II. Claims 19-28, drawn to a method of detecting a polymorphic site in a nucleic acid, in a patient, or determining relatedness, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.

III. Claims 29-31, drawn to an isolated polypeptide comprising a polymorphic site at one or more amino acid residues, classified in class 530, subclass 300. If this Group is elected, then the below summarized sequence election is required.

IV. Claims 32-34, drawn to an antibody that binds specifically to a polypeptide, classified in 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is required.

V. Claim 35, drawn to a method of detecting the presence of a polypeptide having one or more amino acid residue polymorphisms in a subject, classified in class 453, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

VI. Claims 36, 37 and 40, drawn to a method of treating a subject suffering from, a risk for, or suspected of suffering from a pathology ascribed to the presence of a sequence polymorphism in a subject by administering to the subject an effective dose of a second nucleic acid comprising the polymorphic sequence, classified in 514, subclass 44. If this Group is elected, then the below summarized sequence election is required.

VII. Claim 38, drawn to a method of treating a subject suffering from, a risk for, or suspected of suffering from a pathology ascribed to the presence of a sequence polymorphism in a subject by administering to the subject an effective dose of a polypeptide, classified in 514, subclass 2. If this Group is elected, then the below summarized sequence election is required.

VIII. Claim 39, drawn to a method of treating a subject suffering from, a risk for, or suspected of suffering from a pathology ascribed to the presence of a sequence polymorphism in a subject by administering to the subject an effective dose of an antibody, classified in 514, subclass 2. If this Group is elected, then the below summarized sequence election is required.

IX. Claims 41-44, drawn to oligonucleotide array, classified in 422, subclass 68.1. If this Group is elected, then the below summarized sequence election is required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group draw to amino acid/polypeptide sequence, the

Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

The inventions of Groups [I, II and VI]; [III, V, and VII]; [IV and VIII]; and [IX] are distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, II and VI, the critical feature is a nucleic acid molecule. For Groups III, V, and VII, the critical feature is a polypeptide molecule. For Groups IV and VIII, the critical feature is an antibody. For Group IX, the critical feature is an oligonucleotide array. Further, it is acknowledge that various processing steps may cause a peptide of Groups III, V, and VII to be directed as to its synthesis by a polynucleotide set forth in of Group I, however, the completely separate chemical and entity types of the inventions of the polynucleotide and

polypeptide support the undue search burden if they were examined together. Additionally, polypeptide, antibodies, and microarrays have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the four Groupings: Groups [I, II and VI]; [III, V, and VII]; [IV and VIII]; and [IX] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of the nucleic acid molecule containing single nucleotide polymorphism of Group I, the nucleic acid molecule may be utilized in the distinct usages as needed in Group II, a method of detecting a polymorphic site in a nucleic acid, in a patient, or determining relatedness. As needed in Group VI, a method of treating a subject suffering from, a risk for, or suspected of suffering from a pathology ascribed to the presence of a sequence polymorphism, or alternatively, as an antisense therapy. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups III, V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of the nucleic acid molecule containing single nucleotide polymorphism of Group III, the polypeptide may be utilized in the distinct usages as needed in Group V, a method of detecting the presence of a polypeptide having one or more amino acid residue polymorphisms in a subject. As needed in Group VII, a method of treating a subject suffering from, a risk for, or suspected of suffering from a pathology ascribed to the presence of a sequence polymorphism, or alternatively, as in cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of the nucleic acid molecule containing single nucleotide polymorphism, the antibody of Group IV may be utilized in the distinct usages as needed in Group VIII, a method of treating a subject suffering from, a risk for, or suspected of suffering from a pathology ascribed to the presence of a sequence polymorphism, or alternatively, antibodies could be used in immunocytochemical staining for morphological studies, for example. All of these usages are distinct as requiring

distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement e traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
9/26/02

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER